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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,427	07/19/2001	James Aitken	5017-8122	9777

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THOMPSON COBURN, LLP
ONE US BANK PLAZA
SUITE 3500
ST LOUIS, MO 63101

EXAMINER	
CROSS, LATOYA I	

ART UNIT	PAPER NUMBER
1743	

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/909,427	AITKEN ET AL.	
	Examiner	Art Unit	
	LaToya I. Cross	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,9-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,9-16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 August 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *8-5-04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to Applicants' amendments filed on August 5, 2004. Claims 1-6, 9-16 and 18-20 are pending.

Drawings

The drawings were received on August 5, 2004. These drawings are acceptable.

Withdrawal of Rejections from Previous Office Action

- The anticipatory rejection over Friedlander et al is withdrawn in view of Applicants' incorporation of the blade means into independent claim 1. Likewise, all obviousness rejections are also withdrawn.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 1-6, 12, 13 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over US patent 5,660,791 to Brenneman et al in view of Friedlander et al.

Brenneman et al disclose a sensor dispensing instrument for dispensing sensors to detect glucose in blood. The dispenser has a sensor pack loaded therein, wherein the sensor pack contains a plurality of testing elements (34). The dispensing instrument has an outer housing (36) and also has a slide actuator (42) in the housing that is manually slid from a standby position to a testing position to place the sensor in a data processing or display mode (similar to Applicants' pusher and actuation member). The movement of the slide actuator toward the testing position forces the blade (50) of a blade assembly (48) to pierce a portion of

the foil (52) that serves a seal over each of the sensor cavities. After the sensor has been ejected from the sensor cavity, the sensor is in its testing position. Electrical contacts (58) on the sensor are coupled with electronic circuitry (not shown) in the housing. The circuitry may include a microprocessor. After testing, the spent sensor is released from the housing and the slide actuator is manually retracted back to its standby position.

Brenneman et al differ from the instantly claimed invention in that the testing elements of Brenneman et al are disposed in circularly shaped base, not in a stack as recited in claim 1. further, there is no disclosure of a spring urging the testing elements toward the seal.

Friedlander et al teach sensor assembly wherein a plurality of sensors is arranged in a stacked relation inside a tubular magazine. A spring (5) urges each of the sensors upwardly. See figure 3.

It would have been obvious to one of ordinary skill in the art to modify Brenneman et al to have the sensors arranged in a stack to allow more testing elements to be disposed in the housing since the spatial drawbacks of the circular disc are alleviated.

3. Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al and Friedlander et al and further in view of US Patent 4,279,861 to Jessop.

The disclosures of Brenneman et al and Friedlander et al are described above. Neither reference has any disclosure of a ratchet wheel.

Jessop teaches a cartridge for containing test elements for use in performing biological analyses. In moving the test elements out of the cartridge, Jessop teaches using a ratchet wheel as a means for preventing the test elements from moving backwards into the cartridge (i.e. as an anti-backup means). See col. 5, lines 28-51. It would have been obvious to one of ordinary

skill in the art to include a ratchet wheel in the device of Brenneman et al to prevent the test elements from accidentally being moved backwards into the magazines.

4. Claims 11, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brenneman et al and Friedlander et al in view of US Patent 6,534,017 to Bottwein et al.

The disclosures of Brenneman et al and Friedlander et al are described above. Neither reference contains disclosure of a sliding member and no disclosure of the physical description of the test elements to be used.

Bottwein et al teaches a test element storage device comprising a magazine having stacked test elements disposed therein. With respect to claim 11, Bottwein et al teaches using a slide mechanism that serves to remove test elements. The slide is moved incrementally by a length corresponding to the width of the test element. Bottwein et al teaches that the slide can be coupled to a rod, wherein rotation of the rod causes a thrust of the slide and movement of the test elements (col. 6, lines 1-51). It would have been obvious to one of ordinary skill in the art to use a slide mechanism in conjunction with pusher of Brenneman et al to allow the movement of the test elements to be driven by a control unit in an automated manner, where the slide and pusher are both operated by drive units.

With respect to claims 18 and 19, Bottwein et al teaches using testing elements having test zones covered on a portion of the test element. In figure 1B of Bottwein et al, the test elements are shown having test zones (3) on a support (2). The thickness of the test zone (working area) is greater than the thickness of the non-test zones (non-working area). These testing elements are conventionally used in the analytical testing field and it would have been

obvious to one of ordinary skill in the art to use such testing elements in the device of Brenneman et al.

Double Patenting

5. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1, 3-6, 9, 10, 12, 15, 18 and 19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5, 6, 8, 12, 17-21, 25-27 of copending Application No. 09/943,647 in view of Brenneman et al. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims differ from those of the '647 application only in that the instant claims contain an additional blade means.

However, such blade means are taught by Brenneman et al as being suitable for severing a seal around the testing elements. It would have been obvious to one of ordinary skill in the art to incorporate a blade means into the device claimed in the '647 application to provide a means to release the testing element from the moisture tight seal and make the testing element available for use.

In response to Applicants' argument that the '647 application contains a transport member, not recited in the instant claims, the instant claims use the term "comprising" which is open language allowing for the presence of additional components that are not recited.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

3. Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LaToya I. Cross whose telephone number is 571-272-1256. The examiner can normally be reached on Monday-Friday 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Jill Warden
Supervisory Patent Examiner
Technology Center 1700